Wisconsin Department of Health and Family Services

Pharmacy NewsCapsule

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Antipsychotic Potpourri

Doug Englebert
Pharmacy Practice Consultant PRQI

In this article an assortment of antipsychotic medications will be highlighted, including a short refresher regarding the use of Abilify® (aripiprazole). Abilify® was featured in the January/February 2003 edition of this newsletter, but many questions have come up since that time. A review will be beneficial to address these inquiries in this issue.

Abilify® is an antipsychotic that is approved for the treatment of schizophrenia, only. The efficacy in schizophrenia of Abilify® was shown in short four to six week studies.Studies are ongoing for its use in bipolar disease and for psychosis with patients who have Alzheimer's disease.

As with all antipsychotics, Abilify® has the risk of neuroleptic malignant syndrome and tardive dyskinesia. Providers must consider these risks and plan to address them. In addition, Abilify® has side effects of headache, anxiety, insomnia, nausea, vomiting, lightheadedness, somnolence, akathisia, and constipation. Abilify® carries a risk of orthostatic hypotension. Facilities should be aware of these side effects and address individual risks on a resident by resident basis.

Abilify® is a medication that is administered once per day. The typical dosage is 15 mg per day. However, in the elderly population it may be prudent to start at 10 mg. In addition, Abilify® has some drug interactions with ketoconazole, quinidine, fluoxetine (Prozac®), paroxetine (Paxil®), erythromycin, carbamazepine (Tegretol) and grapefruit. Individuals who are on these medications may need to have Abilify® dosage adjustments.

As with most new medications there are still many unknowns. Most advertising will promote this medication as a safer alternative to currently available medications. However, it is essential to remember that there is no risk-free medication and complacency when addressing risk factors may lead to problems.

Risperdal® (risperidone)

In April 2003, Janssen Pharmaceutica Products, L.P., sent out warning letters to pharmacists and physicians about Risperdal®. The letter indicated that the prescribing information was being updated to

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Expiration Dating

Doug Englebert
Pharmacy Practice Consultant PRQI

What about medication expiration dates? Some medications for injection and irrigation are available in multiple dose vials or large irrigation bottles that contain enough medication to be administered multiple times. Often the question is how long a medication is still safely usable once it is opened? This is usually referred to as the expiration date. However, the correct terminology is *beyond-use dating*.

Two factors affect beyond-use dating. One is drug stability. Various medications will have decreased stability once the package is opened. They must be used within a defined time. The second factor is sterility. Typically, medication used for injections must remain sterile. When a sterile medication is exposed to air, the potential exists for bacteria to grow in the opened vial or bottle. Some of these medications have a preservative in them; others do not.

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New Drugs

Doug Englebert Pharmacy Practice Consultant PRQI

Brand Name	Generic Name	Use
Boniva	Ibandronate	For treatment of osteoporosis
Emtriva	Emtricitabine	For treatment of HIV
Factive	Emifloxacin	Antibiotic for bronchitis and pneumonia
Flumist		Flu vaccine
Reyataz	Atazanavir	For treatment of HIV
UloXatral	Alfuzosin	For benign prostatic hyperplasia
Xolair	Omalizumab	For moderate to severe allergy-related asthma
Cardizem LA	Diltiazem	New formulation for hypertension
Oxytrol	Oxybutynin	New patch for overactive bladder
Pravigard PAC	Pravastatin/ aspirin	Combination tablet of pravastatin and aspirin

Medication Errors

Doug Englebert Pharmacy Practice Consultant

The "pool staff phenomena" is commonly on the blame list for providers when medication error patterns identify that a large number of errors occur when pool staff are working. The typical response to lower this error rate is to eliminate pool staff or change staffing agencies. However, it may be beneficial for the facility to take a look at the actual root cause through a quality assurance approach, as the issue may be a systems problem.

The cause of medication errors when pool staff work may be that pool staff do not receive the information or support they need to perform medication pass accurately. For example, when determining the root cause of medication errors, a facility may want to examine if the pool staff is oriented to the medication administration system, oriented to the patients or residents, and to policies the facility uses. By identifying the systemic reason for the errors, the facility can assist both pool staff and permanent staff in proactively preventing medication mistakes.

Focus Drug of the Month

Doug Englebert
Pharmacy Practice Consultant PRQI

Flumist™

Influenza Virus Vaccine Live, Intranasal

Just in time for the 2003 annual immunization for influenza, the FDA recently approved a new medication, Flumist™. Flumist™ is administered nasally, avoiding the need for an injection. However, before you jump for joy, this nasal version is only approved to prevent disease caused by influenza A and B viruses in **healthy children and adolescents, 5-17 years of age, and healthy adults, 18-49 years of age.**

This group of healthy individuals, aged 5-49, is currently not the priority group that should be immunized per the Advisory Committee on Immunization Practices recommendations. Therefore, the majority of individuals that are at high risk of influenza will still need to receive the flu vaccine by injection.

Flumist™ will be available in prefilled single use nasal sprayers. The nasal sprayer almost looks like a syringe in the pictures contained in the manufacturers printed material so it is prudent to separate Flumist™ from other injectable products because Flumist™ should not be injected. Flumist™ must be stored frozen at five degrees Fahrenheit (5 º F).

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reflect that there has been cerebrovascular adverse events, including stroke, in elderly patients with dementia. As mentioned before none of the antipsychotics are FDA approved for use in elderly patients with dementia. As surveyors you may see residents changed from one antipsychotic to another. Psychiatrists and physicians may have different mechanisms to change patients from one antipsychotic to another. Some will just switch the medication. Others will start a new antipsychotic slowly while decreasing the current antipsychotic slowly. In this case you may see patients on two antipsychotics at the same time. Some physicians/psychiatrists may decide to continue residents on the Risperdal® in spite of the warning and risks.

Risperdal-M

There is a new formulation of Risperdal®, called Risperdal®M-Tab. This is an oral disintegrating tablet**.**

Informed Consent and Antisychotic Medication

There have been a number of questions lately from all different types of health care entities (nursing homes, assisted living, hospitals etc.) asking if informed consent forms are required for antisychotic medication. The answer is threefold. First, information about the care an individual is receiving is a basic patient or resident right. Providers should be providing information to their residents or patients about the care they are providing. Second, informed consent is a process. Merely having a form with a signature on it may not indicate the resident or patient is fully informed, especially when the care involves a person with developmental disabilities or mental illness. Third, there are two considerations to informed consent: there may be a regulation requiring informed consent for specific medications and liability concerns for the facility make it favorable to obtain consent.

HFS 94, Wisconsin Administrative Code, addresses informed consent. The next newsletter will have additional information on the sections of HFS 94 that discuss informed consent.

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In summary, the beyond-use date is based on multiple variables. Facilities should base their policies for beyond-use dates on manufacturer guidelines, published literature or their own studies.

In most cases medication will remain stable until the stamped expiration date on the vial or bottle. In some cases the limiting factor will be sterility. For example, large irrigation bottles typically do not have a preservative. If these bottles are opened and are being used for sterile irrigation purposes, most policies support that the bottle be discarded after 24 hours. If facilities are using these large bottles beyond 24 hours for sterile procedures, they should have literature supporting the safety of the irrigation use. Surveyors should check facility policies to determine if they are rationally based and consistently implemented.

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Flumist™ may be thawed in a refrigerator and stored at 36-46 degrees Fahrenheit for no more than 24 hours prior to use. The medication should not be refrozen after thawing.

Healthy adults and children age 9-49 should be vaccinated with one 0.5ml dose per season. Healthy children age 5-8 years who have not previously had Flumist™ should receive two 0.5ml doses 60 days apart. After the first year, children age 5-8 years who previously had Flumist™ will only need one (0.5ml) dose.

Instructions for administration include:

1) Thaw Flumist™,
2) Remove rubber tip protector,
3) Place Flumist™ into nostril and depress plunger,
4) Remove from nostril and remove dose divider clip on plunger,
5) Insert plunger in other nostril and depress plunger.

Please review the manufacturer's guidelines on administration and prescribing Flumist™ once they are finalized.

Side effects of Flumist™ include sinusitis, nasal congestion, rhinitis, runny nose, sore throat, cough, diarrhea and otitis media.

Flumist® will provide a convenient alternative for a subset of people. Those that are at high risk of influenza will still need to receive the influenza vaccination injection this fall.

If there are medications you would like featured in this column, please send an email to Doug at engleda@dhfs.state.wi.us

Consultant's Corner

Doug Englebert *Pharmacy Practice Consultant PRQI*

This section will appear in each issue and will contain information that will answer your questions. If there is a topic about which you want more detailed information, please drop me an email at engleda@dhfs.state.wi.us and I'll research the topic.

1. *What is Abilify®?*

   See the article on Antipsychotic Potpourri.

2. *During a long term care survey it was observed that a resident was on both Abilify® and Risperdal®. Is this safe?*

   First, please remember that most individuals in nursing homes receiving antipsychotics are receiving them because of symptoms of dementia. As noted in the last newsletter, current antipsychotics on the market are not approved for this use. Inherently the use of an antipsychotic for symptoms of dementia could be considered unsafe. Using two antipsychotics at the same time would increase risk of adverse events due to the increased potential in drug interactions and side effects. The use of two antipsychotics at the same time is controversial. The theory behind the use of two antipsychotics is that they each work a little different and therefore the psychiatrist can use less of each drug leading to decrease adverse effects with increased outcomes. However, decreased adverse effects have not been established and many psychiatrists do not support this controversial approach. Long-term care surveyors should look at this practice as they would any antipsychotic started in the facility. If its use is for symptoms of dementia, the facility must identify those symptoms and qualitatively and quantitatively monitor the effect of the antipsychotic on those symptoms. Use of two antipsychotics at the same time should be an additional red flag for investigation.

3. *Can you crush Fosamax® to administer the medication through a G-tube?*

   The drug information on Fosamax® indicates that patients should not chew or suck on the Fosamax® tablet. This recommendation is based on the fact that Fosamax® is a local irritant. By sucking or chewing on the tablet patients may experience esophageal erosion or lesions on their tongue or mouth. However, when Foasamax® is administered through a G-tube the medication bypasses the mouth so the local irritation is not an issue. If facilities do crush Fosamax® they must still follow the administration recommendations per the manufacturer. That means that Fosamax® must only be administered with plain water and the patient must remain upright for at least 30 minutes. The manufacturer has not studied the effectiveness of Fosamax® when administered by G-tube so results cannot be guaranteed. Facilities that do crush Fosamax® should also realize that the medication is an irritant. That means precautions must be taken by employees who crush the medication so that they do not inhale the medication as it is crushed or accidentally rub Fosamax® particles in their eyes since the medication can cause bronchial and eye irritation.

4. *If a resident in a nursing home or intermediate care facility for persons with mental retardation (ICF/MR) is self-administering a medication and has a technique error is that error counted in medication pass task?*

   The guidance to surveyors for nursing homes indicates that a self-administration error is not included in the error calculation but should be investigated under the facility assessment of self-administration of medications. The guidance for ICF/MRs indicates that you must count all medication errors in the medication error rate. However, if an ICF/MR resident has gone through full active treatment demonstrating proficiency in self-administration of the medication and simply is distracted or nervous because a surveyor is watching them, a surveyor should use judgement in evaluating the presumed medication error.

References are available upon request.